Pharmaceutical Quality Documentation and Life Cycle Management in a Data Driven World

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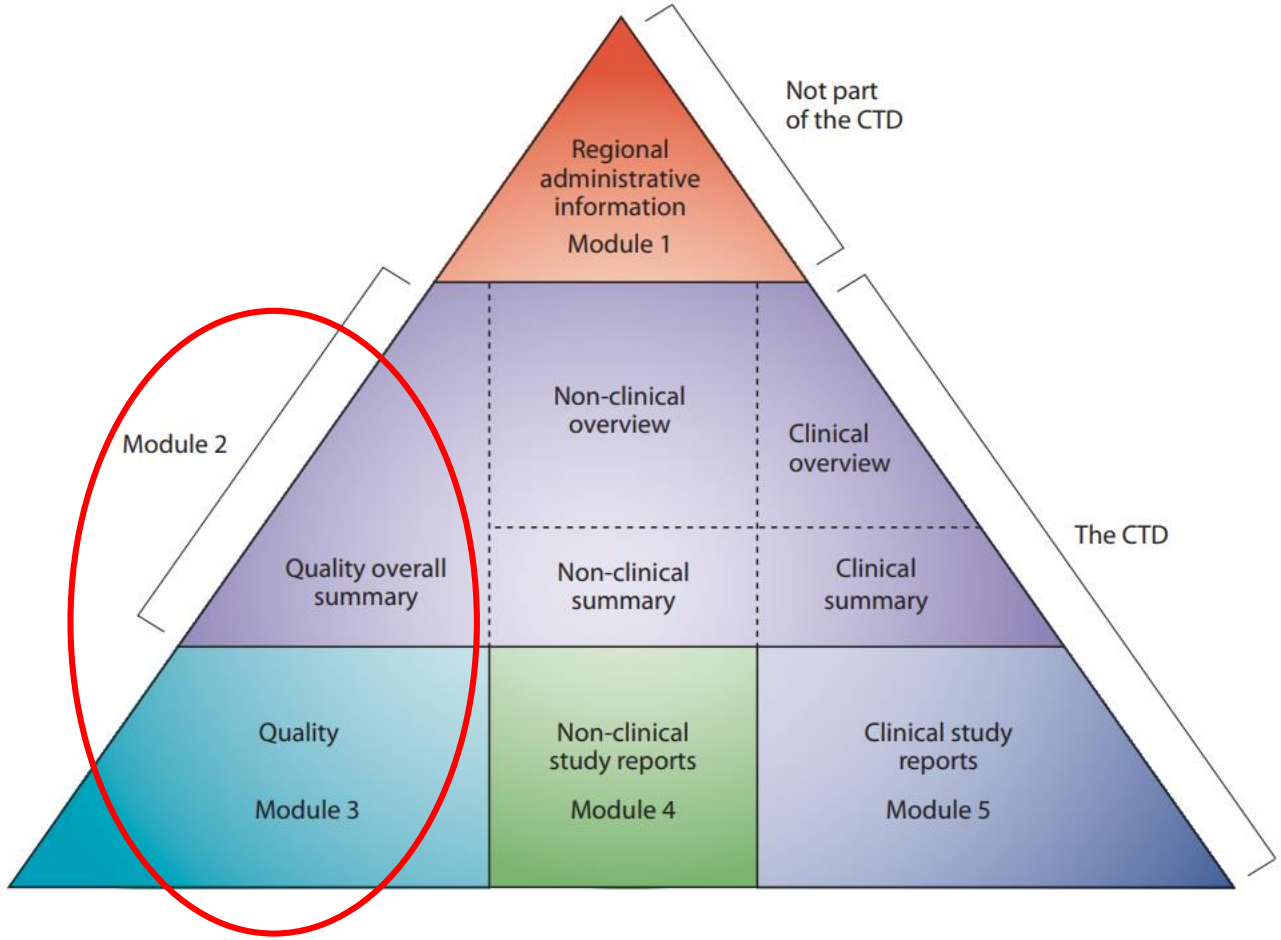
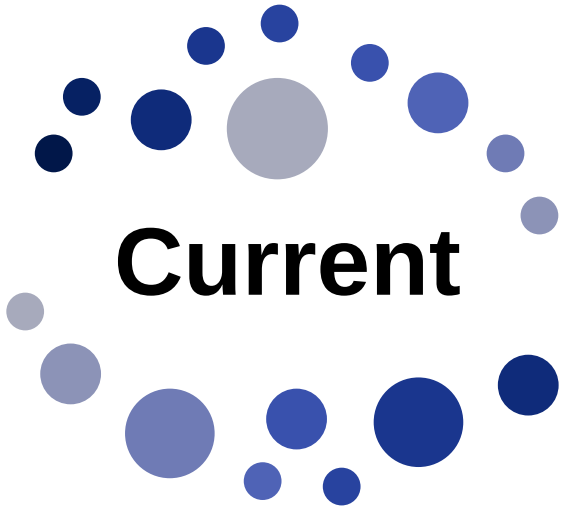
CMC Submissions with ICH M4Q R1 (2002)



- Globally harmonised
  - Except for regional requests
- Clear location of documents in the application

Meant faster access for patients

Trend: Data-Driven Regulatory

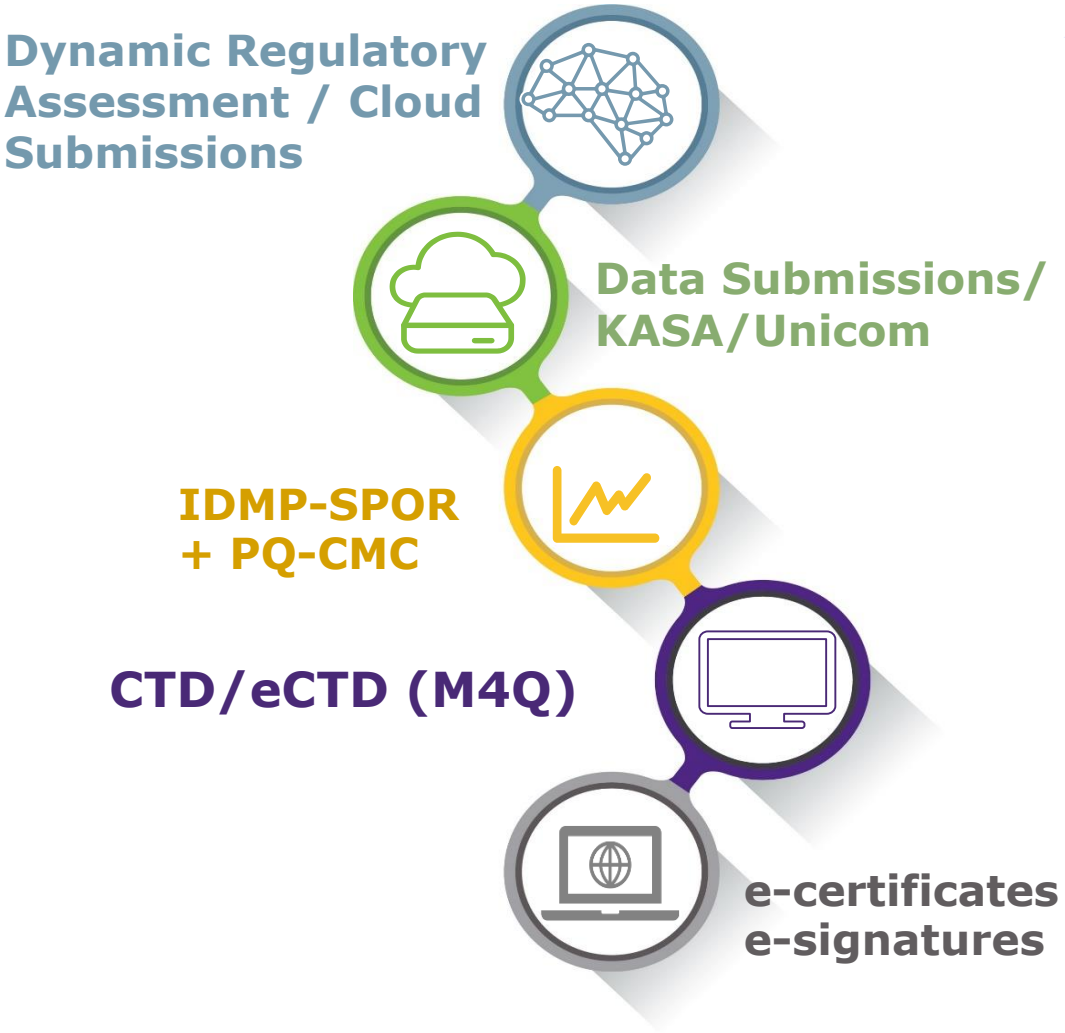


- e-paper (PDF)
- Static data shared at pre-defined stages
- Disparate data repositories
- Country by country submissions

- Harmonized structured data standards with global accessibility
- Increased reliance approach
- Rolling cloud-based data-submissions with dynamic regulatory assessments

*Further Reading:
Nov 2019 – Nature Research - Cloud-based data systems in drug regulation: an industry perspective
Jul 2020 - Pink Sheet article –The last Days of PDF

Stepwise approach to Digital Transformation



transformational

foundational

Transform for greater value and experience to patients:
- Dynamic Regulatory Assessment
- Cloud Submissions
- AI-assisted data analytics to support decision making

Streamline processes
- **ICMRA PQKM** – Pharmaceutical Knowledge Management
- Data submissions, Data Analytics Support, KASA, UNICOM
- Cloud-based storage
- Leveraging digital technologies, automation, to improve processes
- Connect and centralize siloed information

Structure information
- Identification of Medicinal Products (**ISO IDMP**)
- FDA **PQ-CMC** (Phamaceutical Quality - Chemical, Manufacturing, Controls)
- Structured Product Quality Submissions (**ICH SPQS**)

Organize information
- Harmonize submission formats and standards to ICH
- **ICH CTD**, **eCTD**
- **ICH Q12** – Established Conditions, PACMP
- Single Global Dossier

Digitize information: digitally enable e.g., e-certificates, e-signatures, e-consent forms, portals for exchange

Digitalization Projects – Key Takeaways (1 of 2)

ICH eCTD (Global)

Increase priority of eCTD adoption in international markets

- eCTD is a **first step** towards digital transformation (cloud, structured data, M4Q, dynamic, etc)
- ICH M2/M8, starting to discuss **eCTD NextGen**

ISO IDMP (Global)

Beyond FDA, EMA implementation, establish IDMP as the standard for sameness, unique identifiers, substance database, etc

- Collaboration EMA, FDA, WHO, IFPMA for **global identifiers** (GIDWG)
- **Integrate IDMP terms** in M4Q, FHIR, PQ-CMC, etc

SPOR and PLM (EU)

EMA moves to capture product master data (SPOR) through structured forms in their Product Lifecycle Management Portal (PLM)

- First release in 4Q23 with **variation forms**
- **Mandatory use** will be establish through 2024
- Establishing mechanism to make administrative updates **without dossier submissions**

Digitalization Projects – Key Takeaways (2 of 2)

ICH M4Q R2 & SPQS

Modernize CMC CTD, eventually moving to structured data CMC submissions

- M4Q incorporates Q8-Q14 into CTD enabling adoption and more **convergent** implementations
- Introduce **IDMP concepts** into CTD preparing for SPQS

Cloud Based Systems

FDA and EMA planning to move infrastructure to the cloud

- First Cloud Demonstration Project ongoing under PDUFA VII (FDA)
- Cloud platforms for regulatory collaboration emerging

ICMRA PQ-KMS

PQ-KMS encourages transformation to structured data and cloud and increased reliance across regions

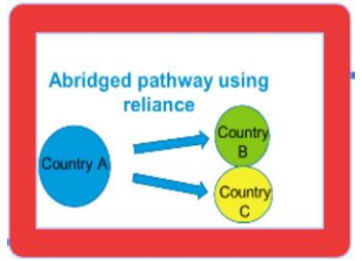
- ICMRA workshop on PQ-KMS highlighted successful pilot and need for cloud platform
- ICH PQKM Task Force is exploring a cloud platform that ICH could manage for regulatory collaboration

Testing the ground: Post-approval change Reliance Pilot using a Single Dossier - Leveraging EMA assessment

- One standard dossier (EU)
- Final EMA CHMP assessment report & Q&A
- No country-specific requirements
- No testing
- One review and Q&A timeline

Reduce global approval timelines
from 2.5 years to 6.5 months

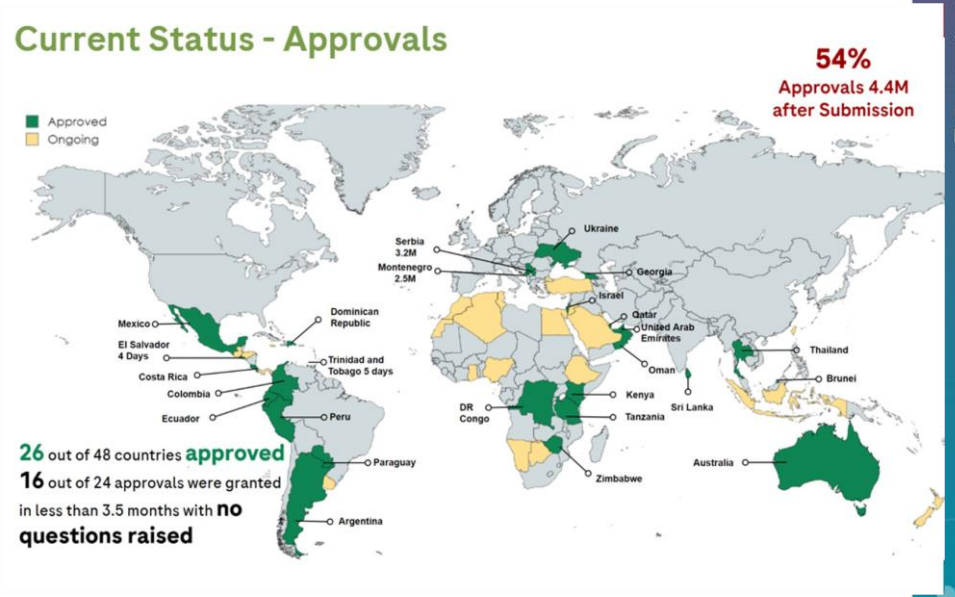
Enhance transparency and build trust



84 COUNTRIES IMPACTED BY THE CHANGE

48 COUNTRIES AGREED to participate in the reliance pilot

=57%
Acceptance Rate



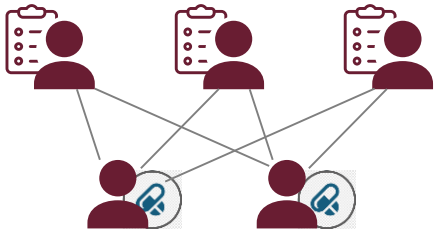
The change will come in stages but is starting today

Value can be realized continuously as the environment evolves

Health Authorities

Sponsors

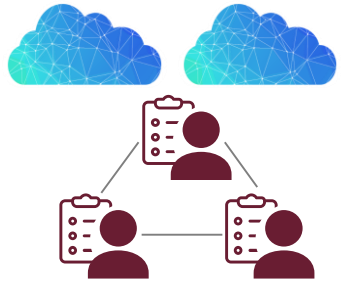
Current/Siloed



1 Point-to-point submissions

- e-paper submission (eCTD)
- Static data shared at pre-defined stages
- Siloed data repositories in industry and jurisdictions

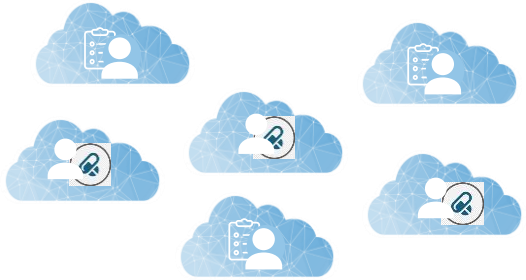
Localized/Limited



2 Limited data submission in cloud

- Harmonized structured data standards with global accessibility
- Use-Case: parallel review and rolling cloud based data submission with dynamic regulatory assessment
- Data analysis standards
- Collaborating with sponsors and HA towards clouds less segmented.

Regional/Expanded



3 Regional adoption

- Standardization of data formats, increase quality, for cross-sponsors exchange/transparency
- Pilot: HAs with auditor instead of approver
- Flexible trial models and RWD framework established
- Automated post marketing safety monitoring with Artificial Intelligence
- Clouds un-siloed and high interoperability

Global/Comprehensive

4 Global Cloud Network

- An organised / harmonised global HA network with local branches
- Sponsors self-control therapeutics quality/efficacy/ safety profiles, with continuous AI based analysis
- Full enablement of most use cases (rolling review, CMC data real-time availability, patient-level submissions)
- One global data model with real-time access for all. Data-driven information and decisions

Doing now what patients need next